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December 4, 2019

VIA ECF ***Redacted Version***

Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

The narrow issue now before the Court concerns Defendants' unilateral redaction of purportedly irrelevant or non-responsive words or phrases from otherwise relevant and responsive documents produced in core discovery, apparently regardless of context or the impact on one's understanding of the document with the redactions. The Court directed each party to identify 20 exemplar documents for *in camera* review. Plaintiffs identify the following 20 exemplar documents for *in camera* review, and submit the redacted versions produced by Defendants herewith *in camera*:

[redacted]

I. RELEVANT LAW

"The majority of the cases . . . clearly state that unilateral redactions based on one party's subjective view of relevancy are improper." *Engage Healthcare Commc'ns, LLC v. Intellisphere, LLC*, No. 12-cv-00787, 2017 WL 3624262, at *3 (D.N.J . Apr. 26, 2017) (collecting cases), *adopted*, 2017 WL 3668391 (D.N.J . Aug. 23, 2017). As the weight of caselaw acknowledges, "[r]edaction is, after all, an alteration of potential evidence. The Federal Rules sanction only very limited unilateral redaction, *see* Fed. R. Civ. P. 5.2." *Krausz Indus., Ltd. v. Romac Indus., Inc.* , No. C10-1204, 2011 WL 13100750, at *3 (W.D . Wash. Aug. 10, 2011) (internal quotations and citation omitted). Further, Rule 34 explicitly mandates the production of "documents" in the form

[1] Document numbers 6 & 7 ([redacted]) are two of several attachments to the same email, at [redacted] Plaintiffs have asked Defendants to produce unredacted ve rsions of entire families of related documents, so the Court has the full context of the particular attachments called out here.

they are ordinarily maintained, not just relevant snippets contained within documents. *See, e.g.*, *Orion Power Midwest, L.P. v. Am. Coal Sales Co.*, No. 2:05-cv-555, 2008 WL 4462301, at *2 (W.D. Pa. Sept. 30, 2008); *see also Bartholomew v. Avalon Capital Grp., Inc.*, 278 F.R.D. 441, 451 (D. Minn. 2011) (Rule 34 concerns production of "documents," and not "particular pictures, graphics, paragraphs sentences, or words."). Unilateral redaction of purportedly irrelevant or non-responsive information for otherwise responsive documents also "gives rise to suspicion that relevant material harmful to the producing party has been obscured" and "tends to make documents confusing or difficult to use." *Doe v. Trump*, 329 F.R.D. 262, 276 (W.D. Wash. Dec. 20, 2018) (internal quotations and citation omitted). For these reasons – and especially where, as here, a confidentiality order is in place to protect sensitive or proprietary information, – courts routinely reject parties' unilateral relevancy or responsiveness redactions. *See, e.g.*, *Engage Healthcare*, 2017 WL 3624262, at *3-4 (collecting cases); *Orion*, 2008 WL 4462301, at *1. The minority of cases allowing redactions unrelated to privilege typically involve prior agreement between the parties, or competitively sensitive information in lawsuits between competitors. *Engage Healthcare*, 2017 WL 3624262, at *3. Neither of these situations applies here.

II. DEFENDANTS' IMPROPER REDACTIONS

Defendants' only productions to date (besides a few organizational charts) have been "core discovery," which includes among other things FDA warning letters, FDA Form 483s, Establishment Inspection Reports (EIRs), and communications with the FDA. *See* 4/29/19 Order (ECF 88). By definition, every document produced in core discovery is relevant to the issues in this litigation. *See, e.g.*, 11/20/19 Tr. at 19.

Defendants' unilateral relevancy/responsiveness redactions to their core discovery productions fall within two broad categories: (i) "block" redactions that obscure substantial portions of a document without explanation, and (ii) redactions of other products, even though the testing and contamination of these products clearly are being discussed along with the valsartan testing and contamination at issue in this litigation. It is important to recognize that Defendants' failure to serve a redaction log as provided in the Order leaves Plaintiffs with little or no instruction of the justification for the redactions in many cases.

A. "Block" Redactions Obscuring Large Portions of Documents Are Improper

Pertinent exemplar documents: [redacted]

Discussion. "Block" redactions excise entire sentences, paragraphs or pages of otherwise responsive documents. Such redactions make it difficult if not impossible for Plaintiffs to identify what was redacted and why, and renders the remainder of the document confusing or difficult to use. *Doe*, 329 F.R.D. at 276. Many of Defendants' core discovery documents feature block redactions.

For instance, [redacted] Aurolife redacted whole paragraphs of this document, without explanation. *See, e.g.*, *id.* at [redacted] Similarly, [redacted]

[redacted] [redacted] Aurolife redacted multiple sentences or paragraphs from [redacted] without any explanation. *Id.* at [redacted]

Plaintiffs cannot tell why these redactions were made, the general types of [redacted] redacted, whether those [redacted] related to valsartan API or some other sartan API, and – perhaps most importantly – whether those [redacted] if relating to other sartan API did or reasonably should have put Aurolife on notice of actual or potential valsartan contamination.

Hetero USA's redactions raise similar issues. Hetero labeled its redactions as information relating to "other products," but most of them are still large block redactions. For instance, every single page of [redacted] is *entirely* redacted.

Another example is [redacted]. This ZHP document discusses responses to an [redacted]. At times, entire paragraphs are redacted. *See, e.g., id.* at [redacted]

Defendants should be required to remove block redactions such as those in the exemplar documents identified herein, and be precluded from using such redactions in the future.

While Defendants will likely argue that Plaintiffs are not entitled to discovery regarding observed cGMP compliance issues with respect to other drugs not at issue in this litigation,[2] this argument lacks merit.

[2] Defendants cannot argue that they should be permitted to redact other drug information because it is a confidential trade secret. First, lack of compliance with cGMP obligations is not a prospective trade secret. Moreover even if that were a trade secret, almost every document

For one, in the EIRs and Form 483s, the FDA makes clear their observations of non-compliance with cGMPs are not meant to be exhaustive or inclusive, but are rather just examples of the types of compliance issues they observed on that one day. *See, e.g.*, FDA Form 483 Frequently Asked Questions ("Q: Is the FDA Form 483 intended to be an all-inclusive list of every possible deviation from law and regulation? A: No, it's not."). [3] Further, many general observations about cGMP violations bear on *all* products made at a given facility, and not any one product in particular. For example, [redacted]. Included among these were [redacted] Similarly, [redacted]

Second, to the extent Defendants' redactions bear upon other sartans, this information is directly probative of whether Defendants should have been on notice that their manufacturing processes were flawed – as ordered by the Court.

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discussed in this brief bears the Restricted Confidential designation, which affords it the highest level of sensitivity. *See, e.g.*, *Orion*, 2008 WL 4462301, at *1.

[3] *Available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed Nov. 26, 2019).

B. Defendants Improperly Excise All References to "Other Products" from FDA Inspection Reports and Communications That Clearly Relate to Valsartan Testing and Contamination

Pertinent exemplar documents: [redacted]

Discussion. FDA inspection documents and communications relating to valsartan API or finished dose testing and contamination are unquestionably relevant and discoverable. [redacted]

Defendants manufacture other sartans at the same facilities as they manufacture valsartan API or finished dose. They even use the same equipment, solvents, and processes to do so. The same employees oversee the production and quality assurance relating to valsartan API and other sartan API. Thus, quality issues overlap of necessity.

While this Court ruled at the November 20 case management conference that Defendants need not produce documents solely relating to other sartans (e.g., losartan, irbesartan, etc.), it excepted from this ruling any information vis-à-vis other sartans API that did or should have put Defendants on notice of potential contamination of valsartan API. *See* 11/20/19 Tr. at 14, 16-17.

As the pertinent exemplar documents make clear, Defendants' "other products" redactions are improper because they clearly relate to deviations and issues that did or should have put Defendants on notice about issues with respect to valsartan. Examples include:

- [redacted]
- [redacted]
- [redacted]

The same is true for other Defendants' "oth er product" redactions. Here are but a few examples for Mylan:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Defendants' redactions of references to [redacted] relating to other sartans that are mentioned in the same FDA documents that also discuss valsartan are improper. Plaintiffs are unduly prejudiced if they cannot discover, let alo ne test in deposition or through expert analys is,

whether troubling issues with other sartans did or should have alerted Defendants to the valsartan contamination at issue in this litigation, especially where the issues overlap with Valsartan.

III. CONCLUSION

There is no justification for Defendants' "block" redactions and "other product" redactions. The Federal Rules and case law do not permit unilateral redaction of documents to excise purportedly irrelevant or non-responsive information. The Discovery Confidentiality Order in this case assuages any confidentiality concerns. Documents relating to valsartan are relevant and discoverable in their entirety, even if they happen to mention another product. Indeed, even if a document does not mention valsartan at all, the Court has already held that documents about other products remain discoverable if they document information that put Defendants on actual or constructive notice of potential valsartan contamination (e.g., "ghost peaks" detected in other sartan API). That is the case here. Defendants should re-produce unredacted versions of their core discovery documents, and be precluded from making similarly inappropriate redactions in future productions.

Respectfully,

ADAM M. SLATER

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